



Silicone Vaginal Dilators



Vaginal Dilator Sets, Product ID: DT-A, DT-B, DT-C

Indications:

The dilators may be used to enlarge the vagina for an examination, a surgical procedure, or for the relief of vaginismus.

Contraindications:

Dilators are contraindicated in acute genital tract infections, pelvic infections, or non-compliant patients.

The physician must advise a pregnant patient if this product may be used.

Caution:

Federal law requires that a physician prescribe this device. Vaginal Dilators are designed for single patient use.

Procedures:

For the indications, it is usually desirable to either support or distend the vaginal canal. Dilators are devices that can be used for this purpose. They have a smooth surface, are flexible, light in weight, shaped to stay in place, and can be easily inserted and removed by the patient.

A vaginal lubricant may be required for the patient's comfort before insertion of a dilator. The physician may suggest K-Y Jelly[®] or Replens[®].

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Instructions:

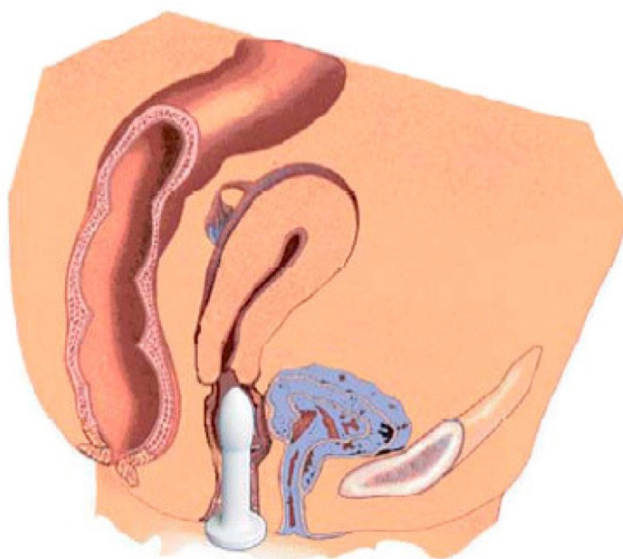
1. Perform a normal pelvic examination prior to the fitting and introduction of a dilator. A pelvic exam helps determine the appropriate size.
2. The length of time a patient should use a vaginal dilator is usually from 5 to 20 minutes per day. The physician may alter the frequency and duration of dilator usage as the prescribed therapy proceeds to the larger sizes in the set.
3. Once the dilator family size or set is determined, the smallest dilator should be inserted into the vagina with the base or flange in the downward position.
4. The dilator should be large enough for its indication, yet not cause any undue pressure of discomfort.
5. The patient should be instructed to gradually increase the dilator size over a suggested period of time until the patient is comfortable with the insertion of the largest size in the set.
6. Tell the patient to report any discomfort immediately.

Removal, Cleaning and Suggested Follow-Up:

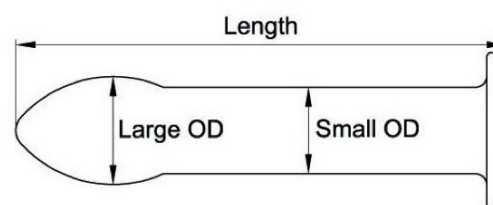
1. To remove a dilator, gently pull downward on the exposed flange until the dilator is completely removed.
2. After removal, the dilator can be cleaned with mild soap and warm water. (The physician may follow the suggested disinfecting procedures.)
3. Discuss the importance of following instructions and the expected length of time for dilator use.
4. Within 24 to 48 hours, be sure the patient is not allergic to the dilators. Examine the vagina and ask the patient if there has been any discomfort, irritation, pressure, sensitivity, or unusual vaginal discharge. Also determine if there has been any improvement in her personal symptoms.
5. Schedule follow-up visits to fit the needs of the patient.

Instructions for The Patient:

Your physician has recognized the need for you to use a set of silicone vaginal dilators. As instructed by your physician, begin your vaginal therapy with the smallest dilator. When it is inserted properly into the vagina, you may be conscious of a mild feeling of pressure. Gradually, over a period of time, your physician will advise you to select the next dilator size for insertion and so on until you are completely comfortable using the largest dilator in the set. At any time, should the dilators become uncomfortable, promptly notify your physician.



Available Family Sizes:



Family A	Length	Small OD	Large OD
DT-A/XL	150.0 mm	30.0 mm	38.0 mm
DT-A/L	138.0 mm	25.5 mm	32.0 mm
DT-A/M	128.0 mm	22.5 mm	28.0 mm
DT-A/S	120.0 mm	19.5 mm	24.0 mm
Family B	Length	Small OD	Large OD
DT-B/XL	95.0 mm	26.0 mm	33.0 mm
DT-B/L	86.0 mm	22.5 mm	28.0 mm
DT-B/M	78.0 mm	19.5 mm	23.0 mm
DT-B/S	75.0 mm	12.5 mm	17.0 mm
Family C	Length	Small OD	Large OD
DT-C/XL	75.0 mm	13.5 mm	18.0 mm
DT-C/L	65.0 mm	12.0 mm	16.0 mm
DT-C/M	60.0 mm	10.5 mm	14.0 mm
DT-C/S	50.0 mm	9.5 mm	13.0 mm

Suggested Disinfecting Procedure for the Physician:

1. Cleaning: submerge in enzymatic cleaner for 20 minutes.
2. Disinfecting: use disinfecting solution like Cidex[®] OPA for 12 minutes and rinse with water thoroughly (be sure to follow manufacturer's instructions)

Or

3. Sterilizing: (Recommended Sterilization Parameters)

Sterilizer	Exposure Temperature	Exposure Time	Minimum Dry Time
Pre-Vacuum (Wrapped)	132°C (270°F)	4 Mins	20 Mins
Pre-Vacuum (Un-Wrapped)	132°C (270°F)	4 Mins	
Gravity Steam	121 °C (250 °F) 132 °C ~135 °C (270 °F ~275 °F)	30 Mins 10 Mins	30 Mins



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